AMENDMENTS TO THE DRAWINGS

The attached set of Replacement Sheets (2) includes Figs. 4a and 5a. Figs. 4a and 5a are cancelled.

Attachment: Annotated Copies Showing Cancellation (2)

REMARKS

Claims 20-38 are currently pending in the current application. The alleged new matter introduced into the disclosure in the Amendment filed September 22, 2004 is objected to, and claims 20-38 stand rejected.

By way of this Amendment, the alleged new matter is cancelled; claims 20, 23-25 and 29 are amended; and claim 28 is cancelled.

35 U.S.C. § 132 Rejections

The Examiner objects to the alleged new matter introduced into the disclosure in the Amendment filed September 22, 2004. In particular, the Examiner asserts that all inclusions of "an integral sensor device can be sealed into the seam of a blood bag or seam of another type of primary container" and the additions of Figs. 4a and 5a are new matter not supported by the original disclosure. Accordingly, the Examiner requires that the alleged new matter be cancelled. Although Applicants respectfully disagree with the new matter objection under 35 U.S.C. § 132, the application is amended in a manner that is consistent with the Examiner's requirement to cancel the alleged new matter in reply to the Office Action. The amendment to the specification and drawings places the specification and drawings back to their presentation as originally filed absent the amendments submitted September 22, 2004.

35 U.S.C. § 102 Rejections

The Examiner rejects claims 20-26, 28 and 36-38 under 35 U.S.C. § 102(e) as being anticipated by United States Patent No. 6,315,767 to Dumont et al. (hereinafter "the Dumont patent"). The Examiner states that the Dumont patent discloses a device which comprises a biosensor (30), a separation barrier consisting of a gated pore membrane (18) and a sensor compartment located between the wall (20) and the membrane (18). Additionally,

the Examiner states that the Dumont patent discloses the gated pore to be occluded by an erodible substance sensitive to pH or solvent concentration (see "Summary" section). Furthermore, the Examiner recites other matter disclosed in the Dumont patent on page 3 of the Office Action.

In response to the Examiner's rejection to claims 20-26, 28 and 36-38 under 35 U.S.C. § 102(e), the claims in the application are amended to cover the invention and are supported by the disclosure in the application. In particular, claim 20 has been amended further to define the biosensor, the biosensor enclosure and the separation barrier elements of the sensor device. The biosensor is further defined as comprising a receptor bound on a solid substrate as previously recited in claim 29. Support for this amendment is found in Paragraph [0038], lines 3 and 4, and also in Paragraph [0040]. The biosensor enclosure is further defined in accordance with the disclosure in the application. The separation barrier is further defined to include the recitation from cancelled claim 28, namely that the separation barrier is selected from the group consisting of a fibril membrane, a microporous membrane and a capillary-pore membrane. Additionally, the separation barrier is further defined to include having at least one pore allowing fluid communication between the interior and exterior of the sensor compartment. Support for the aforementioned amendment further to define the separation barrier is found generally throughout the disclosure and particularly in Paragraph [0036] of the application. Additionally, claim 25 is amended to include a recitation directed towards contact with water to further define the response associated with the responsive material as claimed in the previous dependent claim 24. Support for this amendment to claim 25 is found in Paragraph [0032] of the application. Furthermore, the amendments to claims 21, 23, 24, 27 and 29 are made in order to clarify claim dependencies as well as provide

proper antecedent bases for the recitations in the claims. Finally, claim 28 is cancelled because it has been incorporated into claim 20.

In view of the amendments to the claims in the application, the sensor device now claimed has a separation barrier comprising a membrane selected from the group consisting of a fibril membrane, a microporous membrane and a capillary pore membrane. The separation barrier is characteristically a gated-pore membrane with open pores as claimed in Claim 20 (See Paragraph [0050], Lines 5 and 6); gated pores that open when water contacts the membrane and erodes the responsive material to open the gate and allow for free exchange of molecules across the membrane as claimed in Claims 22 through 25 (See Paragraph [0032], lines 1-7); and gated pores that remain closed until the responsive material erodes in response to a predetermined stimulus such as change in pH, by-product of cellular metabolism, presentation of a secreted bacteriologic toxin, and any other stimulus (See Paragraph [0027], lines 20-26). As emphasized in Figure 1, however, the gated pore need not contain a material which erodes if the pore itself changes structure upon appropriate stimulus. The sensor device, when positioned within a container, is used for aseptic detection of molecular changes of the contents of the container. Although an important embodiment of the present invention is intended to report the status of material inside a container such as a sealed container, the present biosensors are useful even in situations other than inside a sealed container. In fact, depending on the dimensions, the biosensor enclosure can actually be one of the gated pores, so that all the claimed elements of the invention reside within a porous membrane which can in turn be placed at the end of a probe or rod, etc. By this construction, claim 20 recites a biosensor compartment which can intrinsically be a pore in the separation barrier. *See*, for instance, Example 9, which illustrates that fluorescein-based indicators are contemplated for use in the present invention. A fluorescein-based detector may thus be

bound to the interior of a pore in a separation barrier, bound to a bead or other substrate, or both. The resulting separation barrier, or a segment thereof, can be used in conjunction or affixed to a rod or probe, in addition to residing within or as a part of a sealed primary container.

In contrast, the Dumont patent teaches a device with a membrane having a plurality of pores, which are filled with an erodible substance responsive to selected characteristics of blood in a bag containing the device. In particular, the Dumont patent teaches that the pores are preferably filled with an erodible substance (24) which is responsive to, and erodible upon exposure to, certain environmental conditions or a selected characteristic of a blood product (26) contained within the inner volume of the bag (12), such as a pH level or decreased glucose level. *See* the Dumont patent, col. 4, lines 12-16. Particularly, the Dumont patent teaches that the erodible substance (24) contained within the pores (22) begins to dissolve when the pH of the stored blood product drops to 6.4 and is completely eroded away when the pH of the blood product reaches 6.2. *See* the Dumont patent, col. 4, lines 24-31. The Dumont patent does contemplate that the membrane may be composed of a material responsive to a selective characteristic of the blood product, such that the unfilled pores themselves are responsive to the selected characteristic, having a relatively smaller pore size at a first value of the selected characteristic and a relatively larger pore size at a second value of the selected characteristic. *See* the Dumont patent, col. 2, line 65 to col. 3, line 4. Even in the aforementioned contemplated membrane configuration taught by the Dumont patent, the membrane is required to be actively responsive to a selected characteristic of blood in a blood bag.

However, the Dumont patent fails to teach or disclose a separation barrier forming a portion of the sensor compartment, wherein a separation barrier selected from the

group consisting of a fibril membrane, a microporous membrane and a capillary-pore membrane. Additionally, the Dumont patent fails to teach or suggest a biosensor comprising a receptor bound on a solid substrate. Accordingly, the cell storage maintenance and monitoring system as disclosed and claimed in the Dumont patent does not include the sensor device comprising a "biosensor comprising a receptor bound on a solid substrate," nor a sensor device having "a separation barrier selected from the group consisting of a fibril membrane, a microporous membrane and a capillary-pore membrane" whereby "the separation barrier having at least one pore allowing fluid communication between the interior and the exterior of the sensor compartment" as disclosed and claimed in the present application. The Dumont patent, therefore, clearly fails to anticipate or even suggest the sensor device disclosed and claimed in independent claim 20 and those that depend thereon in the application. Applicants, therefore, respectfully request reconsideration of the Examiner's rejection to claims 20-26, 28 and 36-38 under 35 U.S.C. § 102(e).

35 U.S.C. § 103 Rejections

The Examiner rejects claims 29, 30 and 32-35 under 35 U.S.C. § 103(a) as being unpatentable over the Dumont patent in view of United States Patent No. 5,194,393 to Hugle et al. (herinafter "the Hugle patent"). In view of the amendments to independent claim 20, Applicants submit that claims 29, 30 and 32-35, which depend from claim 20, are patentable over the Dumont patent in view of the Hugle patent. Applicants submit that the Dumont patent fails to teach or suggest a sensor device as previously discussed. In addition, the Hugle patent discloses a sensor for the detection of analyte molecules based on fluorescence energy transfer. The Hugle patent clearly fails to disclose a sensor device as disclosed and claimed in amended claim 20 and those that depend thereon. Accordingly, the Dumont patent and the Hugle patent, either taken alone or in combination, fail to render the

invention as claimed in claims 20-28 and 30-38 unpatentable for obviousness under 35 U.S.C. § 103(a). Applicants, therefore, respectfully request reconsideration of the Examiner's rejection to claims 29, 30 and 32-35 under 35 U.S.C. § 103(a).

The Examiner rejects claim 31 under 35 U.S.C. § 103(a) as being unpatentable over the Dumont patent in view of United States Patent No. 5,814,449 to Schultz et al. (hereinafter "the Schultz patent"). In view of the amendment to independent claim 20, Applicants submit that claim 31, which depends indirectly from claim 20, is patentable over the Dumont patent in view of the Schultz patent. Applicants submit that the Dumont patent fails to teach or suggest the sensor device as previously discussed. In addition, the Schultz patent teaches a homogenous affinity assay for quantitative drug and metabolite determination. The Schultz patent clearly fails to disclose the sensor device as disclosed and claimed in amended claim 20 and those that depend thereon. Accordingly, the Dumont patent and the Schultz patent, either taken alone or in combination, fail to render the invention as claimed in claim 31 unpatentable for obviousness under 35 U.S.C. § 103(a). Applicants, therefore, respectfully reconsideration of the Examiner's rejection to claim 31 under 35 U.S.C. § 103(a).

The Examiner rejects claim 27 under 35 U.S.C. § 103(a) as being unpatentable over the Dumont patent in view of United States Patent No. 5,976,827 to Jeffrey et al. (hereinafter "the Jeffrey patent"). In view of the amendment to independent claim 20, Applicants submit that claim 27, which depends from claim 20, is patentable over the Dumont patent in view of the Jeffrey patent. Applicants submit that the Dumont patent fails to teach or suggest the sensor device as previously discussed. Additionally, the Jeffrey patent teaches a sensor which provides an environment to culture microbial organism colonies from a fluid sample for later microbial detection and quantification. Accordingly, the Dumont

patent and the Jeffrey patent, either taken alone or in combination, fail to render the invention as claimed in claim 27 unpatentable for obviousness under 35 U.S.C. § 103(a). Applicants, therefore, respectfully request reconsideration of the Examiner's rejection to claim 27 under 35 U.S.C.§ 103(a).

In view of the foregoing, Applicants believe that claims 20-28 and 30-38 are patentable over the cited prior art and are in condition for allowance. Allowance of claims 20-28 and 30-38 is respectfully requested.

A Supplemental Information Disclosure Statement (IDS) is submitted contemporaneously herewith.

Respectfully submitted,

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